

Ex 15 - CAH_MDL2804_02465982-6053

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

2012 DEA MOA for CAH

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., ("Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all 28 Cardinal DEA registered distribution facilities.

BACKGROUND

1. Cardinal is registered with DEA at 28 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" or "the Act"). See Appendix A.
2. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"). See Appendix B.
3. Cardinal's Lakeland distribution facility ("Cardinal Lakeland") is registered with DEA as a distributor of Schedule II-V controlled substances at 2045 Interstate Drive, Lakeland, Florida 33805, with an expiration date of May 31, 2012.
4. On February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland. See Appendix C.
5. The Order to Show Cause referenced above alleged, among other things, that:
 - a. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;
 - b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and
 - c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.

STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, as well as the facts alleged in the Government's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, constitute grounds under which DEA could revoke the DEA registration of Cardinal Lakeland. Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate. In lieu of continuing proceedings to revoke the DEA registration of Cardinal Lakeland, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters involving the conduct described in the Order to Show Cause, as well as DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this administrative matter.
2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:
 - a. Conduct alleged in the February 2, 2012 Order to Show Cause ("Order to Show Cause"), and in DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D;
 - b. Failure to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels, including failing to conduct site visits of its retail pharmacy chain customers on or before May 14, 2012;
 - c. Failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before May 14, 2012; and
 - d. Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.
3. Effect of 2008 MOA. The obligations contained in the 2008 MOA are superseded by the obligations contained within this Agreement.
4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of Cardinal.

- a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1.f. This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this Agreement do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.
- b. Within 120 days of the Effective Date of this Agreement, for all states, excluding Florida, Cardinal will commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances that are known to be diverted, or should be known to be diverted, at the time of the orders that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted. For Florida pharmacies, retail and chain, Cardinal, within 20 days of the Effective Date of this Agreement, will commence these site visit procedures. Cardinal will also employ additional field inspectors to perform investigations of Florida pharmacies.

Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.

- c. Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.

- d. Cardinal will enhance existing processes and practices for conducting due diligence reviews of pharmacies, chain and retail, including those located in Florida.
- e. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, as well as tramadol, through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).
- f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.
- g. Cardinal agrees to the continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014, so long as the provisions of II.2.c are met.
- h. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b).
- i. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement

authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

- j. Any material breach by any Cardinal facility of subsections II.1.a-f of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate of registration for that facility.
- k. Cardinal agrees that it will dismiss, with prejudice, the pending appeal by Cardinal in Case No. 12-5061 as well as the pending petition for review by Cardinal in Case No. 12-1126 in the United States Court of Appeals for the District of Columbia Circuit. Cardinal agrees that it will also dismiss, with prejudice, Case No. 12-cv-185 in the United States District Court of the District of Columbia.

2. Obligations of DEA.

- a. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and as described in subsection II.1.g. of this Agreement. DEA agrees to waive the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Offices.
- b. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.
- c. If Cardinal is in compliance with the terms of this Agreement, DEA agrees that it will take appropriate steps to lift the suspension of Cardinal Lakeland's DEA registration and, if needed, to grant any requisite registration renewal on May 14, 2014.

3. Joint Obligations of the Parties.

- a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Cardinal Lakeland in *The Matter of Cardinal Health*, DEA Docket No. 12-32.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

- a. Release Cardinal, together with its subsidiary entities, distribution facilities, and registrants that are listed in Appendix A, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 for the conduct alleged in the Order to Show Cause, DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, and for the conduct alleged in this Agreement; and
- b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of May 14, 2012, and the review of the reports and records Cardinal submitted to DEA prior to May 14, 2012. This release applies only to administrative actions brought before or by the Agency.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. DEA expressly reserves the right to pursue civil action, through the United States Attorney's Office, against Cardinal for the "Covered Conduct" as described in this Agreement. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Cardinal is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

- a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any liability other than administrative claims released in Paragraph II.4.a. and b.;
or
- c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.
2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.
5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.
6. Notices. All communications and notices to Cardinal pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:
 - a. Gilberto Quintero, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614-757-6597; email: gilberto.quintero@cardinalhealth.com;
 - b. With copy to: Steve Falk, Executive Vice-President and General Counsel, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614-652-7325; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.
8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.
10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of Cardinal Health:

Craig S. Morford
Chief Legal and Compliance Officer

Dated:

**On Behalf of the United States Department
of Justice, Drug Enforcement
Administration:**

Michele M. Leonhart
Administrator ,

Dated: 5/14/12

Wendy H. Goggin
Chief Counsel

Dated: 5/14/12

APPENDIX A

(Cardinal Distribution Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.
2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.
3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.
4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (dba Specialty Pharmaceutical).
5. 2512 Westcott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.
6. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.
7. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.
8. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.
9. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (dba Specialty Pharmaceutical).
10. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.
11. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.
12. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.
13. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

14. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.
15. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.
16. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.
17. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.
18. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.
19. 4 Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.
20. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW0263056.
21. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.
22. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.
23. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.
24. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.
25. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (dba Parmed Pharmaceuticals).
26. Centro Internacional de Distribucion, EDIF#10, CARR. 869 KM. 4.2, Guaynabo, Puerto Rico, operating under DEA registration number RB0374683 (dba Borschow Hospital & Medical Supplies).
27. 15 Ingram Boulevard, Suite 140, La Vergne, TN, operating under DEA registration number RC0403802.
28. 152-35 10th Avenue, Whitestone, NY, operating under DEA registration number RK0416900 (dba Kinray, Inc.).

APPENDIX B

(2008 MOA Referenced in Background at Para. 2 of this Agreement)

2012 DEA Show Cause/ISO



**U.S. Department of Justice
Drug Enforcement Administration**

Office of the Administrator

Springfield, Va 22152

FEB 02 2012

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

**ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION**

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Cardinal") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RC0182080, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Cardinal an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, or a location designated by the Administrative Law Judge, on April 3, 2012 (if Cardinal requests such a hearing), as to why DEA should not revoke Cardinal's DEA Certificate of Registration RC0182080, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(f), because Cardinal's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Cardinal is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA Certificate of Registration RC0182080 expires by its terms on August 31, 2012.

2. On September 30, 2008, Cardinal entered into an Administrative Memorandum of Agreement (MOA) with DEA agreeing to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Furthermore, Cardinal "acknowledg[ed] and agree[d] that the obligations undertaken ... do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for

controlled substances.” MOA, at 3.

3. Despite the MOA, the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

4. Since at least 2009, Cardinal’s largest purchasers of oxycodone products have been retail pharmacies in the State of Florida engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and outside the usual course of professional practice.

- a. From January 1, 2008 through December 31, 2011, Automation of Reports and Consolidated Orders System (“ARCOS”) data shows that Cardinal’s sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. In 2010 and 2011 alone, Cardinal sold 10.9 million dosage units of oxycodone to its top four customers. From 2008 to 2009, Cardinal’s sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal’s sales to its top four retail pharmacy customers increased approximately 162%.

The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal’s Florida retail pharmacies, which received, on average, approximately 5,347 dosage units of oxycodone per month.

- b. From January 1, 2008 through December 31, 2011, Cardinal sold over 5 million dosage units of oxycodone to its top customer, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy # 00219 (“CVS 219”) (DEA Certificate of Registration BC5289055). On average, Cardinal sold CVS 219 approximately 137,994 dosage units of oxycodone per month during the same time period.
- c. From January 1, 2008 through September 30, 2011, Cardinal sold approximately 3.4 million dosage units of oxycodone to Gulf Coast Pharmacy (former DEA Certificate of Registration BG8830223). On average, Cardinal sold Gulf Coast Pharmacy approximately 96,664 dosage units of oxycodone per month during the same time period.
- d. From January 1, 2008 through December 31, 2011, Cardinal sold approximately 2.2 million dosage units of oxycodone to Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #05195 (“CVS 5195”) (DEA Certificate of Registration BC6988298). On average, Cardinal sold CVS 5195 approximately 58,223 dosage units of oxycodone per month during the same time period.

- e. From January 1, 2008 through September 30, 2011, Cardinal sold approximately 2.1 million dosage units of oxycodone to Caremed Health Corporation, d/b/a Brooks Pharmacy ("Brooks Pharmacy") (former DEA Certificate of Registration BC7126457). On average, Cardinal sold Brooks Pharmacy approximately 59,264 dosage units of oxycodone per month during the same time period.

5. Notwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers. Furthermore, Cardinal failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 C.F.R. § 1301.74(b). In addition, Cardinal's conduct described herein violated the provisions of the Administrative Memorandum of Agreement.

6. In addition to the legal authorities cited above, the following Final Order provides a summary of the legal basis for this action: *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that Cardinal's continued registration is inconsistent with the public interest. Under the facts and circumstances described herein, it is my conclusion that Cardinal's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

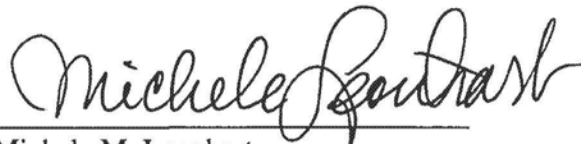
PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Cardinal possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Cardinal's DEA Certificate of Registration RC0182080 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Cardinal may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Cardinal fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Cardinal may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Cardinal decline to file a request for a hearing or, should Cardinal request a hearing and then fail to appear at the designated hearing, Cardinal shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.

A handwritten signature in black ink, reading "Michele M. Leonhart". The signature is fluid and cursive, with the first name "Michele" being more prominent and the last name "Leonhart" written in a more compact, connected style.

Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Dedra S. Curteman, Counsel for the Government
Carrie A. Bland, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrisette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant
or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

2008 DEA MOA for CAH